



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/444,144	11/20/99	HOWELL	M CYT0001

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HM22/0329

EXAMINER

HELMS, L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/29/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Advisory Action

Application No.

09/444,144

Applicant(s)

Howel et al

Examiner

Larry R. Helms Ph.D.

Group Art Unit

1642



THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☒ expires 3 months from the mailing date of the final rejection.
- b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on \_\_\_\_\_ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on 23 Mar 2001 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☒ The proposed amendment(s):

☒ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☐ will not be entered because:

- ☐ they raise new issues that would require further consideration and/or search. (See note below).
- ☐ they raise the issue of new matter. (See note below).
- ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

☒ Applicant's response has overcome the following rejection(s):

112 second paragraph

- ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:

see attached sheet

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: none

Claims objected to: none

Claims rejected: 1-3, 5, 10-27, 34, 37, 38, 40-42, and 50-56

- ☐ The proposed drawing correction filed on \_\_\_\_\_ ☐ has ☐ has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Other

*Attachment to Advisory Action*

1. The rejection of claims 1-3, 5, 10-27, 34, 37-38, 40-42, and newly added claims 50-56 under 35 U.S.C. 103(a) as being unpatentable over Lentz (U.S. Patent 4,708,713, issued 11/24/87, IDS #4) and further in view of Selinsky et al (Immunology 94:88-93, 5/1998, IDS #4) and Maraskovsky et al (U.S. Patent 6,017,527, filed 12/12/96) is maintained.

The response filed 3/23/01 has been carefully considered but is deemed not to be persuasive. The response states that "Lentz is, at best, ambiguous on the point of separating plasma from whole blood" (see page 5 of response). In response to this argument, as admitted by the applicants in the specification on page 21, lines 19-24, means for initially fractionating the biological fluid into cellular component and the acellular component was known in the art at the time of filing. The response further states that the declaration of Howell and Selinsky have provided comments in support of Applicants position regarding the references of Lentz and Selinsky. The declaration of Howell and Selinsky has been carefully considered but is deemed not to be persuasive. The declaration states that there are a variety of conventional approaches to remove soluble proteins, and the ex-vivo approach claimed is not conventional. In response to this argument, Selinsky et al clearly teaches that the soluble protein sTNFRI which is an inhibitor has been shown to be removed by Ultrapheresis (see introduction page 88 of Selinsky et al). Ultrapheresis is clearly an ex-vivo method. The response further states "since, by the Examiner's admission, Maraskovsky is cited only for the teaching of immobilized antibody on the surface such as beads for the purpose of removing cells that contain a specific antigen, this reference does not make up for the deficiencies of the combination of Lentz and Selinsky et al" (see page 6 of response). In response to this argument, it is true that the Markovsky et al cited for teaching antibodies immobilized on a bead for removal of antigens from a blood sample and administering

the altered blood sample to the individual to enhance an immune response, as stated in the Office

Action of 8/18/00.

  
SHEELA HUFF  
PRIMARY EXAMINER